NOV 1 9 2002

K013694

SECTION 16: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

16.1 SUBMITTER INFORMATION

a. Company Name:	Nidek, Inc.
b. Company Address:	47651 Westinghouse Drive Fremont, CA 94539
c. Company Phone: Company Facsimile:	(510) 226-5700 (510) 226-5750
d. Contact Person:	Hiro Matsuzaki Quality Assurance Manager
e. Date Summary Prepared:	November 18, 2002

16.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Nidek Advanced Vision Information System (NAVIS)
b. Classification Name:	Radiological Image Processing System 21 CFR 892.2050 86 NFJ

16.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
AETmed, S.P.A.	AETmed Image Processing Software	K012093	09/21/2001

16.4 DEVICE DESCRIPTION

The Nidek Advanced Vision Information System (NAVIS) is a computer technology software that collects, stores and maintains patient data information.

NAVIS provides real-time review of diagnostic patient information from a number of ophthalmic medical instruments at any PC workstation. NAVIS incorporates patient data, examination data, office scheduling and billing into one system.

The Nidek Advanced Vision Information System (NAVIS) contains a main core software program and a number of optional software modules that can be installed. The additional software modules support the number of application instruments that can be used with NAVIS in order to directly transfer and enhance the patient examination data. Additional software modules include the Cell Analysis Eyebank module, the Fundus Measurement module and a software module to allow for networking of several PC workstations and internet access.

16.5 SUBSTANTIAL EQUIVALENCE

The Nidek Advanced Vision Information System is substantially equivalent to the AETmed Image Processing Software is terms of image processing, patient data collection and data management. NAVIS is also comparable to IFA Systems ifa System device and the Topcon Instruments Corporation IMAGEnet device in terms of their use in ophthalmic practice to collect and store clinical data. These devices transfer patient data from computerized diagnostic ophthalmic instruments via direct connections or through networks.

16.6 INDICATIONS FOR USE

The Nidek Advanced Vision Information System (NAVIS) is a software program intended for use in collection, storage and clinical information management of patient data, diagnostic data and the images from computerized diagnostic instruments through direct connection with the instruments, or through networks.

16.7 TECHNOLOGICAL CHARACTERISTICS

The fundamental technical characteristics of NAVIS are similar to those of the predicate devices. The functionality and the indications for use for NAVIS are similar to the predicates. NAVIS and the predicate devices are patient databases that collect and store data from connected medical ophthalmic instruments. NAVIS differs from the predicate devices in that it contains an image manipulation module, which contains functions for retinal imaging and slit lamp imaging. The Imaging module can also contain the Cell Analysis and Fundus Measurement software for advanced data analysis.

16.8 PERFORMANCE DATA

Performance testing was conducted on the Nidek Advanced Vision Information System. System and supported instrument testing was completed based on product specifications and hazard effects determined from the risk analysis. The Nidek Advanced Vision Information System performed as intended and has thus is deemed substantially equivalent to the predicate device and comparable to other ophthalmic patient database devices.

16.9 CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission. The Nidek Advanced Vision Information System (NAVIS) has been tested and found to perform as intended. NAVIS has been compared to a legally cleared predicate device and found to be substantially equivalent. Comparisons to other ophthalmic patient database software have also been performed and NAVIS was found to have equivalent functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2002

NIDEK, Inc.
c/o Ms. Carol White
Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, CA 92630

Re: K013694
Trade/Device Name: Nidek Advanced Vision Information System (NAVIS)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: NFJ
Dated: November 5, 2002
Received: November 7, 2002

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATION FOR USE

510(k) Number: To Be Assigned By FDA K013694

Device Name: Nidek Advanced Vision Information System (NAVIS)

Indications for Use: The Nidek Advanced Vision Information System (NAVIS) is a software program intended for use in the collection, storage and clinical information management of patient data, diagnostic data and the images from computerized diagnostic instruments through direct connection with the instruments, or through networks.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11-15-2002

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K013694

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)